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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/957,012	09/20/2001	John Lezdey	1434-K	3483

7590 07/29/2003

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Clearwater, FL 33764

EXAMINER

COE, SUSAN D

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 07/29/2003

9

Please find below and/or attached an Office communication concerning this application or proceeding.

FILE Wrg

Office Action Summary

Application No.

09/957,012

Applicant(s)

LEZDEY ET AL.

Examiner

Susan Coe

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 13 May 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-11 and 21 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-11 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☒ Interview Summary (PTO-413) Paper No(s). 6.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1654

DETAILED ACTION

1. The amendment filed May 13, 2003, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 1 and 12-20 have been cancelled.
3. Claim 21 has been added.
4. Claims 2-11 and 21 are pending.
5. In the response filed May 13, 2003, applicant states that alpha-1-antitrypsin, secretory leucocyte protease inhibitor, and alpha-2-macroglobulin are all obvious over each other. Therefore, the election of species requirement set forth in Paper No. 3 (dated December 26, 2002) is withdrawn.

Claim Rejections - 35 USC § 103

6. Claims 2-9 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable WO 00/51623 in view of US Pat. No. 4,496,689 and WO 99/55310 for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that it is known in the art that the teaching of WO '623 is incorrect because it is known that alpha-1-antitrypsin cannot be administered orally because it is degraded by bile acids in the gastrointestinal system. However, the rejection is not based on WO '623 alone. It is based on the combination of WO '623, US '689 and WO '310. The supplementary references teach that it was known in the art at the time of the invention that it is desirable to stabilize alpha-1-antitrypsin. The combination of these reference

Art Unit: 1654

results in a method of treating rheumatoid arthritis by orally administering a stabilized alpha-1-antitrypsin. Therefore, applicant's invention is properly considered obvious based on what was known in the art at the time of the invention.

7. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 00/51623, US Pat. No. 4,496,689 and WO 99/55310 as applied to claims 2-9 and 21 above, and further in view of US Pat. No. 4,743,596 for the reasons set forth in the previous Office action.

Applicant does not specifically address this rejection. Therefore, it is still considered valid for the reasons stated above.

8. Claims 4-9 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable US Pat. No. 5,114,917 in view of US Pat. No. 4,496,689 and WO 99/55310 for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that US '917 is not directed towards treating the same type of rheumatoid arthritis as that claimed by applicant because US '917 only treats inflammation related rheumatoid arthritis. However, US '917 provides a general teaching of using alpha-1-antitrypsin to treat inflammation related to rheumatoid arthritis. According to the Merck Manual excerpt submitted by applicant, inflammation is a characteristic symptom of rheumatoid arthritis (see "Symptoms and Signs" section). Therefore, US '917 is considered to provide a teaching that is applicable to all types of rheumatoid arthritis. Thus, the claims are still considered to be obvious in view of the combination of the references.

9. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,114,917, US Pat. No. 4,496,689 and WO 99/55310 as applied to claims 4-9 and 21 above,

Art Unit: 1654

and further in view of US Pat. No. 4,743,596 for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. In response to applicant's argument that the steroid used in the prior art is used for inflammation and not Interleukin I, the fact that applicant has recognized another advantage which would flow naturally from following the suggestion of the prior art cannot be the basis for patentability when the differences would otherwise be obvious. See *Ex parte Obiaya*, 227 USPQ 58, 60 (Bd. Pat. App. & Inter. 1985). The combination of the references teaches adding a steroid to the active protein. Therefore, the claims are properly considered obvious even if the reason for the combination is different than applicant's reason for combination.

10. Claims 2 and 3 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Pat. No. 5,114,917, US Pat. No. 4,496,689 and WO 99/55310 as applied to claims 4-9 and 21 above, and further in view of US Pat. No. 5,362,733 for the reasons set forth in the previous Office action.

Applicant does not specifically address this rejection. Therefore, it is still considered valid for the reasons stated above.

11. No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

Art Unit: 1654

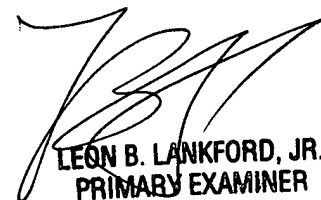
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (703) 306-5823. The examiner can normally be reached on Monday to Thursday from 8:00 to 5:30 and on alternating Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brenda Brumback, can be reached on (703) 306-3220. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Susan Coe, Examiner
July 17, 2003



LEON B. LANKFORD, JR.
PRIMARY EXAMINER